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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/532,319 | 04/22/2005 | Ellen J Baron | 222310-US | 9127 |

22829 7590 01/04/2008
ROCHE MOLECULAR SYSTEMS INC
PATENT LAW DEPARTMENT
1145 ATLANTIC AVENUE
ALAMEDA, CA 94501

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| EXAMINER |
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JOHANNSEN, DIANA B

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| ART UNIT | PAPER NUMBER |
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1634

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| MAIL DATE | DELIVERY MODE |
|-----------|---------------|

01/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**UNITED STATES DEPARTMENT OF COMMERCE****U.S. Patent and Trademark Office**

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Alexandria, Virginia 22313-1450

| APPLICATION NO./ CONTROL NO. | FILING DATE | FIRST NAMED INVENTOR / PATENT IN REEXAMINATION | ATTORNEY DOCKET NO. |
|---------------------------------|-------------|---|---------------------|
| 10532319 | 4/22/05 | BARON ET AL. | 222310-US |

ROCHE MOLECULAR SYSTEMS INC
PATENT LAW DEPARTMENT
1145 ATLANTIC AVENUE
ALAMEDA, CA 94501

EXAMINER

Diana B. . Johannsen

| ART UNIT | PAPER |
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1634

20071228

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

See enclosed Notice of Non-Compliant Amendment and attachment.

Diana B. Johannsen
Primary Examiner
Art Unit: 1634

**Notice of Non-Compliant
Amendment (37 CFR 1.121)**

Application No.

10/532,319

Examiner

Diana B. Johannsen

Applicant(s)

BARON ET AL.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on 25 October 2007 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
 - ☐ B. New paragraph(s) should not be underlined.
 - ☐ C. Other _____.
- ☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
- ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
 - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
 - ☐ C. Other _____.
- ☒ 4. Amendments to the claims:
- ☐ A. A complete listing of all of the claims is not present.
 - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
 - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
 - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☒ E. Other: claims not properly marked up - see enclosed explanation.
- ☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.
2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action. If any of above boxes 1. to 4. are checked, the correction required is only the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121.

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

Failure to timely respond to this notice will result in:

Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

NA

Legal Instruments Examiner (LIE), if applicable

Telephone No.

Attachment to Notice of Non-Compliant Amendment

1. The amendment to the claims filed on October 25, 2007 does not comply with the requirements of 37 CFR 1.121(c) because the claims are not properly marked up to indicate changes made relative to the immediate prior version of the claims.

Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) *Claims.* Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (e.g., Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean

version, *i.e.*, without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, *i.e.*, without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

2. In the instant case, the claim set provided October 25, 2007 is not properly marked up so as to illustrate changes relative to the immediate prior version of the claims. For example, in claim 1, an entire method step of "determining whether....a first predetermined cut off value" is underlined; however this step appears to be identical to the "determining" step that appeared in the prior version of the claims (such that the text is not "new" text that should be underlined). If applicant intended to modify the text of the "determining" step, only the changes to the text should be illustrated by markings (alternatively, the deletion of the entire "determining" step could be illustrated by strike-through, and a new (underlined) step added). Correction is required for compliance with 37 CFR 1.121(c).

3. Since the reply filed on October 25, 2007 appears to be *bona fide*, applicant is given a TIME PERIOD of **ONE (1) MONTH** or **THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to submit an amendment in compliance

Application/Control Number:
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Art Unit: 1634

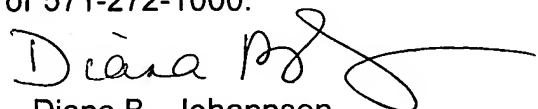
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with 37 CFR 1.121 in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Diana B. Johannsen
Primary Examiner
Art Unit 1634